Delaware Joins 44 Other States and District of Columbia in Settlement Over Misleading Information Regarding Hip Implants

Delaware Attorney General Kathy Jennings announced Friday that she and 45 other Attorneys General reached a settlement with Johnson & Johnson and its subsidiary DePuy Orthopaedics, Inc., to resolve allegations that DePuy unlawfully promoted two of its metal-on-metal hip implant devices.

Attorneys General allege that DePuy engaged in deceptive practices in its promotion of the ASR XL and Pinnacle Ultamet hip implant devices by making misleading claims as to their longevity, also known as survivorship. DePuy advertised that the ASR XL hip implant had a survivorship of 99.2 percent at three years when the National Joint Registry of England and Wales reported a 7 percent revision rate at three years. Similarly, DePuy promoted the Pinnacle Ultamet as having a survivorship of 99.8 percent and 99.9 percent survivorship at five years when the National Joint Registry of England and Wales reported a 2.2 percent three-year revision rate in 2009 increasing to a 4.28 percent five-year revision rate in 2012.

Some patients who required hip implant revision surgery to replace a failed ASR XL or Pinnacle Ultamet implant experienced persistent groin pain, allergic reactions, tissue necrosis, and a build-up of metal ions in the blood. The ASR XL was recalled from the market in 2010. DePuy discontinued its sale of the Pinnacle Ultamet in 2013.

“Accurate and up to date information for both doctors and

patients is critical to effective health care," said **Attorney General Jennings**. "This settlement helps ensure that doctors can continue making the most informed, medically appropriate decisions they can about patient care."

As part of the settlement, DePuy has agreed to the entry of a cease-and-desist order that requires the company to reform how it markets and promotes its hip implants in Delaware. Under the order, DePuy shall:

- Base claims of survivorship, stability or dislocations on scientific information and the most recent dataset available from a registry for any DePuy hip implant device.
- Maintain a post market surveillance program and complaint handling program.
- Update and maintain internal product complaint handling operating procedures including training of complaint reviewers.
- Update and maintain processes and procedures to track and analyze product complaints that do not meet the definition of Medical Device Reportable Events.
- Maintain a quality assurance program that includes an audit procedure for tracking complaints regarding DePuy Products that do not rise to the level of a Medical Device Reportable Event but that may indicate a device-related serious injury or malfunction.
- Perform quarterly reviews of complaints and if a subgroup of patients is identified that has a higher incidence of adverse events than the full patient population, determine the cause and alter promotional practices as appropriate.

The total value of the settlement is $120 million. Delaware will receive $1.3 million, with the money going to the state's Consumer Protection Fund, which funds consumer protections investigations and activities.

Deputy Attorney General David Weinstein of the Consumer Protection Unit led Delaware's efforts on this matter.

The complete cease-and-desist order can be found here.

The investigation was led by the Attorneys General of Texas and South Carolina with an Executive Committee consisting of the Attorneys General of Florida, Indiana, North Carolina, Ohio, Pennsylvania, and Washington. Also participating in the settlement are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, and Wisconsin.